Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1951.02
True Name	Tenosynovitis Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Enterovax - International Free Trade Co. Enterovax - Intervet Mexico S.A. de C.V. Enterovax - Intervet South Africa (Pty) Ltd. Enterovax - Intervet South Africa (Pty) Ltd. - Merck Sharpe and Dohme (MSD) Enterovax - Intervet Thailand Ltd Enterovax - MSD Salud Animal Columbia S.A.S. Enterovax - Merck Animal Health Enterovax - No distributor specified Merck Animal Health
Date of Compilation Summary	November 16, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Reovirus
Study Purpose	To demonstrate effectiveness against Tenosynovitis (viral arthritis) caused by Reovirus.
Product Administration	Coarse Spray Cabinet
Study Animals	Day of Age Chickens
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	January 15, 1992

Study Type	Efficacy
Pertaining to	Reovirus
Study Purpose	To demonstrate effectiveness against Tenosynovitis (viral arthritis) caused by Reovirus
Product Administration	Drinking Water
Study Animals	Chickens
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 18, 1988

Study Type	Efficacy
Pertaining to	Reovirus
Study Purpose	To demonstrate effectiveness against Tenosynovitis (viral arthritis) caused by Reovirus
Product Administration	Drinking Water
Study Animals	Seven-Day-of-Age Chickens
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	January 15, 1992

Study Type	Safety
Pertaining to	Tenosynovitis Vaccine, Modified Live Virus
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	Coarse Spray Cabinet and Drinking Water
Study Animals	Chickens
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 8, 1992